

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES


Application No.: 10/068,812 Confirmation No.: 8436
Applicant : Richard J. Greff
Filed : February 4, 2002
TC/A.U. : 1611
Examiner : Ghali, Isis A D
Title : CROSS-LINKED GELATIN COMPOSITION COMPRISING A
WETTING AGENT
Docket No. : 1001.2216102
Customer No. : 11050

APPEAL BRIEF FILED UNDER 37 C.F.R. § 41.37

Mail Stop Appeal Brief - Patents
Assistant Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

CERTIFICATE FOR ELECTRONIC TRANSMISSION: The undersigned hereby certifies that this paper or papers, as described herein, are being electronically transmitted to the U.S. Patent and Trademark Office on this 7th day of December, 2010.

By _____


JoAnn Lindman

Dear Sirs:

Pursuant to 37 C.F.R. § 41.37, Appellant hereby submits this Appeal Brief in furtherance of the Notice of Appeal filed on October 7, 2010, and of the Notice of Panel Decision from Pre-Appeal Review dated mailed November 5, 2010. Appellant authorizes the fee prescribed by 37 C.F.R. § 41.20(b)(2) in the amount of \$540 to be charged to Deposit Account No. 50-0413. Permission is hereby granted to charge or credit Deposit Account No. 50-0413 for any errors in fee calculation.

TABLE OF CONTENTS

I.	REAL PARTY IN INTEREST.....	3
II.	RELATED APPEALS AND INTERFERENCES.....	3
III.	STATUS OF CLAIMS.....	3
IV.	STATUS OF AMENDMENTS.....	3
V.	SUMMARY OF CLAIMED SUBJECT MATTER.....	4
VI.	GROUND OF REJECTION TO BE REVIEWED ON APPEAL.....	6
VII.	ARGUMENT.....	6
A.	CLAIMS 22-33 AND 42 ARE PROPERLY SUPPORTED UNDER 35 U.S.C. § 112, FIRST PARAGRAPH.	6
B.	CLAIMS 22-25, 27-30, 32, 33, AND 42 ARE PATENTABLE OVER PAWELCHAK ET AL., U.S. PATENT NO. 4,292,972, UNDER 35 U.S.C. § 102(b).	7
1.	<i>A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.</i>	7
2.	<i>Conclusion.</i>	11
C.	CLAIM 26 IS PATENTABLE OVER PAWELCHAK ET AL., U.S. PATENT NO. 4,292,972, IN VIEW OF YASUSHI ET AL., JP 02- 182259, UNDER 35 U.S.C. § 103(a).	11
1.	<i>All words in a claim must be considered in judging the patentability of that claim against the prior art.</i>	12
2.	<i>If an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious.</i>	12
D.	CLAIM 31 IS PATENTABLE OVER PAWELCHAK ET AL., U.S. PATENT NO. 4,292,972, IN VIEW OF SONG ET AL., EP 0 568 334, UNDER 35 U.S.C. § 103(a).	12
E.	CONCLUSION.....	12
VIII.	CLAIMS APPENDIX.....	14
IX.	EVIDENCE APPENDIX.....	18
X.	RELATED PROCEEDINGS APPENDIX.....	19

I. REAL PARTY IN INTEREST

The real party in interest is the assignee of record, Boston Scientific Scimed, Inc., a corporation organized and existing under and by virtue of the laws of Minnesota, and having a business address of One Scimed Place, Maple Grove, MN 55311-1566. An assignment from the inventor, Richard J. Greff, conveying all right, title and interest in the invention to Sub-Q, Inc. has been recorded at Reel 013007, Frame 0656 and a note and Purchase Warrant has been recorded at Reel 015156, Frame 0484 with a subsequent Assignment of Assignors' Interest from Sub-Q, Inc. to Boston Scientific Scimed, Inc. which has been recorded at Reel 018420, Frame 0029.

II. RELATED APPEALS AND INTERFERENCES

There are no other known appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

Claims 22-38, 42, 43, and 45-47 are pending in the application of which claims 34-38, 43, and 45-47 were previously withdrawn with traverse. Claims 39-41 and 44 have been canceled from the application.

Claims 22-33 and 42 stand finally rejected under 35 U.S.C. 112, first paragraph.

Claims 22-25, 27-30, 32, 33, and 42 stand finally rejected under 35 U.S.C. § 102(b) as being unpatentable over Pawelchak et al., U.S. Patent No. 4,292,972.

Claim 26 stands finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Pawelchak et al., U.S. Patent No. 4,292,972 in view of Yasushi et al., JP 02-182259.

Claim 31 stands finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Pawelchak et al., U.S. Patent No. 4,292,972 in view of Song et al. (identified as EP 5568 334 ('334), but believed to be EP 0 568 334)

Claims 22-33 and 42 of the application are currently being appealed.

IV. STATUS OF AMENDMENTS

No amendments subsequent the final rejections of June 8, 2010 have been presented.

V. SUMMARY OF CLAIMED SUBJECT MATTER*

The invention generally relates to a preformed, biocompatible, hemostatic, cross-linked gelatin composition which has a first hydration time having a wetting agent coated on at least a substantial portion of the surface thereof, wherein the preformed, biocompatible, hemostatic, cross-linked gelatin composition having a wetting agent coated on at least a substantial portion of the surface thereof has a second hydration time which is less than the first hydration time. The wetting agent in question is soluble in a non-aqueous solvent and the surface coating of wetting agent is applied by briefly exposing the preformed, biocompatible, hemostatic, cross-linked gelatin composition to a coating solution including the wetting agent and the non-aqueous solvent.

Turning now to independent claim 22 which relates to a biocompatible, hemostatic, cross-linked gelatin composition comprising: a preformed cross-linked gelatin sponge (see, for example, specification page 6, line 20 to page 7, line 23, page 8, lines 4-9 and lines 25-27, page 9, line 14 to page 11, line 27, page 13, lines 6-14, page 18, lines 10-23, page 22, lines 7-22, page 24, line 22 to page 25, line 7, page 26, lines 5-22, page 28, lines 7-27, page 32, lines 2-8); and a wetting agent (see, for example, specification page 5, line 9 to page 6, line 28, page 7, lines 5-23, page 9, line 3 to page 10, line 9, page 11, line 9 to page 12, line 9, page 13, lines 6-14, page 14, lines 4-20, page 15, lines 1-18, Table 1, page 17, lines 28-31, page 18, lines 10-23, page 19, lines 1-3, Table 2, page 22, lines 8-25, page 23, lines 4-22, Table 3, page 25, lines 4-13, Table 4, page 26, lines 5-23, Table 5, page 27, lines 18-28, page 28, lines 1-21, page 32, lines 2-8, page 35, lines 4-6, Table 8); wherein the wetting agent (see, for example, specification page 5, line 9 to page 6, line 28, page 7, lines 5-23, page 9, line 3 to page 10, line 9, page 11, line 9 to page 12, line 9, page 13, lines 6-14, page 14, lines 4-20, page 15, lines 1-18, Table 1, page 17, lines 28-31, page 18, lines 10-23, page 19, lines 1-3, Table 2, page 22, lines 8-25, page 23, lines 4-22, Table 3, page 25, lines 4-13, Table 4, page 26, lines 5-23, Table 5, page 27, lines 18-28, page 28, lines 1-21, page 32, lines 2-8, page 35, lines 4-6,

* The references to the specification and drawings provided herein are exemplary, and are not deemed to be limiting as support may be found throughout the specification and in many of the Figures.

Table 8) decreases hydration time of the gelatin sponge (see, for example, specification page 6, line 20 to page 7, line 23, page 8, lines 4-9 and lines 25-27, page 9, line 14 to page 11, line 27, page 13, lines 6-14, page 18, lines 10-23, page 22, lines 7-22, page 24, line 22 to page 25, line 7, page 26, lines 5-22, page 28, lines 7-27, page 32, lines 2-8) and the wetting agent (see, for example, specification page 5, line 9 to page 6, line 28, page 7, lines 5-23, page 9, line 3 to page 10, line 9, page 11, line 9 to page 12, line 9, page 13, lines 6-14, page 14, lines 4-20, page 15, lines 1-18, Table 1, page 17, lines 28-31, page 18, lines 10-23, page 19, lines 1-3, Table 2, page 22, lines 8-25, page 23, lines 4-22, Table 3, page 25, lines 4-13, Table 4, page 26, lines 5-23, Table 5, page 27, lines 18-28, page 28, lines 1-21, page 32, lines 2-8, page 35, lines 4-6, Table 8) is soluble in a non-aqueous solvent (see, for example, specification page 11, line 18 to page 12, line 9, page 22, lines 16-24, page 24, lines 25-28); wherein the wetting agent (see, for example, specification page 5, line 9 to page 6, line 28, page 7, lines 5-23, page 9, line 3 to page 10, line 9, page 11, line 9 to page 12, line 9, page 13, lines 6-14, page 14, lines 4-20, page 15, lines 1-18, Table 1, page 17, lines 28-31, page 18, lines 10-23, page 19, lines 1-3, Table 2, page 22, lines 8-25, page 23, lines 4-22, Table 3, page 25, lines 4-13, Table 4, page 26, lines 5-23, Table 5, page 27, lines 18-28, page 28, lines 1-21, page 32, lines 2-8, page 35, lines 4-6, Table 8) is coated on at least a substantial portion of the surface of the preformed gelatin sponge (see, for example, specification page 6, line 20 to page 7, line 23, page 8, lines 4-9 and lines 25-27, page 9, line 14 to page 11, line 27, page 13, lines 6-14, page 18, lines 10-23, page 22, lines 7-22, page 24, line 22 to page 25, line 7, page 26, lines 5-22, page 28, lines 7-27, page 32, lines 2-8) by soaking the preformed gelatin sponge (see, for example, specification page 6, line 20 to page 7, line 23, page 8, lines 4-9 and lines 25-27, page 9, line 14 to page 11, line 27, page 13, lines 6-14, page 18, lines 10-23, page 22, lines 7-22, page 24, line 22 to page 25, line 7, page 26, lines 5-22, page 28, lines 7-27, page 32, lines 2-8) in a coating solution (see, for example, specification page 22, lines 22-24, 25, lines 7-9, page 26, lines 5-23) including the wetting agent (see, for example, specification page 5, line 9 to page 6, line 28, page 7, lines 5-23, page 9, line 3 to page 10, line 9, page 11, line 9 to page 12, line 9, page 13, lines 6-14, page 14, lines 4-20, page 15, lines 1-18, Table 1, page 17, lines 28-31, page 18, lines 10-23, page 19, lines 1-3, Table 2, page 22, lines 8-25, page 23, lines 4-22, Table 3, page 25, lines 4-13,

Table 4, page 26, lines 5-23, Table 5, page 27, lines 18-28, page 28, lines 1-21, page 32, lines 2-8, page 35, lines 4-6, Table 8) and the non-aqueous solvent (see, for example, specification page 11, line 18 to page 12, line 9, page 22, lines 16-24, page 24, lines 25-28).

VI. GROUND OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether claims 22-33 and 42 are properly supported under 35 U.S.C. § 112, first paragraph.
2. Whether claims 22-25, 27-30, 32, 33, and 42 are patentable over Pawelchak et al.
3. Whether claim 26 is patentable over Pawelchak et al. in view of Yasushi et al.
4. Whether claim 31 is patentable over Pawelchak et al. in view of Song et al.

VII. ARGUMENT

A. CLAIMS 22-33 AND 42 ARE PROPERLY SUPPORTED UNDER 35 U.S.C. § 112, FIRST PARAGRAPH.

It is believed that the disclosure of forming a wetting agent surface coating on a preformed cross-linked gelatin foam composition by briefly soaking cubes of a preformed cross-linked gelatin foam composition in a non-aqueous isopropanol solution of the wetting agent is described in Example 2 beginning at page 18 as discussed in detail in the paper of August 3, 2010. The preformed sponge cubes are formed initially as a bun from which cubes of about 1.5-2.0 cm were cut. Examples 3-5 employ similar methodology. Possession may be shown by describing an actual reduction to practice of the claimed invention. A specification may describe an actual reduction to practice by showing that the inventor constructed an embodiment or performed a process that met all the limitations of the claim and determined that the invention would work for its intended purpose. (MPEP 2163. II., 3., (a).) The examples include multiple instances in which the claimed preformed cross-linked

coated gelatin sponges were made, coated, as tested to demonstrate not only utility, but also a range of conditions under which the invention was capable of delivering the asserted benefit.

It is possible that the Examiner may have been commenting on what was perceived to be a lack of an explicit statement to the effect that the foamed, cross-linked, and dried gelatin compositions of the disclosure constitute a sponge as that term would be understood by one of ordinary skill in the art and that the cubes cut from the bun prior to coating would be understood to be preformed sponges.

What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d at 1384, 231 USPQ at 94. >See also *Capon v. Eshhar*, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1085 (Fed. Cir. 2005) (“The ‘written description’ requirement must be applied in the context of the particular invention and the state of the knowledge.... As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution.”).< If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. See, e.g., *Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116; *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating “the description need not be in *ipsis verbis* [i.e., “in the same words”] to be sufficient”). (*Ibid.*)

The Examiner did not rebut Appellant’s response to the rejection in the Advisory Action and it is believed that the rejection has been effectively overcome and should be overruled.

B. CLAIMS 22-25, 27-30, 32, 33, AND 42 ARE PATENTABLE OVER PAWELCHAK ET AL., U.S. PATENT NO. 4,292,972, UNDER 35 U.S.C. § 102(b).

1. *A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.*

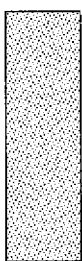
Pawelchak teaches a lyophilized foam sponge product formed from hydrocolloids, gelatin, pectin, and sodium carboxymethyl cellulose. The product is produced by forming an aqueous colloidal dispersion of hydrocolloids; aerating or foaming; freezing; and lyophilizing. (Abstract) Attention is directed to the lack of cross-linking, the lack of

a non-aqueous solvent system, and the lack of a wetting agent in the initial disclosure. The disclosed variations do not overcome the initial deficiencies. The disclosure of Pawelchak with regard to wetting agents/surfactants/dispersants and the like is limited to claim 30 and the text at col. 4, lines 47-57:

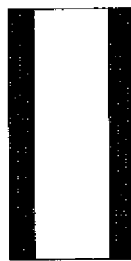
“30. The process of claim 16 wherein a surfactant is added to the colloidal dispersion to stabilize and enhance the quality of the foam.”

“A surface tension modifier such as sodium hexametaphosphate or natural or synthetic surfactants such as lecithin and polyoxyethylene derivatives of sorbitan fatty acid esters such as Tween 60 can be added to the colloidal dispersion to stabilize the gas suspension and enhance the quality of the foam. Such agents can be added in varying amounts depending upon their surfactant ability but in general will vary from about 10% to about 100% by weight of the solids already present in the colloidal dispersion.”

Such agents are added to the colloidal dispersion prior to foaming and thus, if present at all, are dispersed uniformly throughout the material of the sponge. The foamed or aerated colloidal dispersion, with any added surface tension modifier uniformly dispersed therein, is then poured into containers and frozen. At this point, the foam is an aqueous composition, not a preformed gelatin sponge, and is not cross-linked. Following lyophilization, “The lyophilized hydrocolloid foam product can be cross-linked so as to reduce its solubility and absorbability.” (Col. 5, lines 17-19.) In the absence of the claimed structures having a coated surface, Pawelchak necessarily cannot disclose the performance of such structures and so cannot teach a decrease in hydration time resulting from the presence of such structures. As illustrated in the sketches below, an article of Pawelchak at left may optionally include, dispersed within the hydrocolloid portion (white) of the foam, a surface tension modifier (black dots) which serves to stabilize the foam prior to cross-linking and cutting into individual sponges. By contrast, an article of the pending claims illustrated below right has a cross-linked gelatin portion (white) and a surface coating (black) on the preformed cross-linked gelatin portion.



Pawelchak



Pending claim 22

Pawelchak discloses that the crosslinking agent may be added to the aerated or foamed colloidal dispersion which optionally may contain a surface tension modifier uniformly dispersed therein. In the alternative, the freeze dried lyophilized colloidal dispersion which optionally may contain a dispersed surface tension modifier may be exposed to formaldehyde or glutaraldehyde vapor or ultraviolet radiation. (Col. 5, lines 24-27.) Accordingly, Pawelchak does not disclose a wetting agent coating on at least a substantial portion of the surface of a preformed cross-linked gelatin sponge. The surface coating imparts a novel structure to the coated foam sponge which produces a higher concentration of the wetting agent on the surface of the cross-linked foam sponge. The use of a non-aqueous solvent prevents irreversible damage to the foam which may result from contact with water as discussed at page 24, lines 25-26.

Appellant has carefully reviewed the Examples provided by Pawelchak for departures from the initially described foam sponge preparation. Example 1 has no surface tension modifier and is not cross-linked. Example 2 has no surface tension modifier and is not cross-linked, although it “can be sterilized by exposure to gamma radiation at 1.5 Mrads”. There is no assertion that such exposure cross-links the foam sponge or that it is subsequently treated with a cross-linking agent or surface tension modifier. Example 3 was prepared in the manner of Example 2 and has no surface tension modifier and is not cross-linked. Example 4 was prepared in the manner of Example 2 and has no surface tension modifier and is not cross-linked. Examples 5-20 were prepared in the manner of Examples 1 or 2 and have no surface tension modifier and are not cross-linked. Example 21 was prepared in the manner of Example 3, but with the addition of formaldehyde in water to the aerating foam prior to freezing and lyophilizing which is said to cross-link one or more of the (unspecified) hydrocolloids; however no surface tension modifier was added before or after freezing and lyophilizing.

Example 22 teaches the addition of lyophilized thrombin to the composition of Example 1 prior to foaming and thus has no surface tension modifier and is not cross-linked. Example 23 describes the evaluation of the “hemostatic and bioabsorbability of a sponge product of the invention as compared with the commercially available product Gelfoam® (Upjohn)”. The material to which the commercially available product was compared was that of Example 1 which again has no surface tension modifier and is not cross-linked. Appellants direct attention to the lack of a surface tension modifier, as identified by Pawelchak, within the examples as well as the lack of data related to hydration times.

While some embodiments of Pawelchak may employ similar materials in producing hydratable sponges, the cited Tween 60 is only added to the precursor to a foam which may subsequently lyophilized and/or cross-linked. Thus Pawelchak does not appear to disclose a cross-linked foam with a coating of a wetting agent on the surface thereof, wherein said wetting agent is soluble in a non-aqueous solvent.

Accordingly, Pawelchak does not disclose “a preformed cross-linked gelatin sponge; and a wetting agent; wherein the wetting agent decreases hydration time of the gelatin sponge and the wetting agent is soluble in a non-aqueous solvent; wherein the wetting agent is coated on at least a substantial portion of the surface of the preformed gelatin sponge by soaking the preformed gelatin sponge in a coating solution including the wetting agent and the non-aqueous solvent”, as recited in independent claim 22. No preformed cross-linked sponge of Pawelchak is coated, much less coated by exposing it to a non-aqueous solution of a wetting agent which is soluble in a non-aqueous solvent. There is no indication in the disclosure of Pawelchak that a post-applied surface coating is structurally equivalent to a material uniformly dispersed within a sponge and it would not be understood to be equivalent by one of ordinary skill in the art. The Examiner clearly errs in asserting that the composition is anticipated because it contains similar components without properly taking into account that the materials of Pawelchak are not arranged as required by the claim. The introduction of the wetting agent from a non-aqueous solution after the formation of the crosslinked sponge imparts a distinctly different structure in which the wetting agent is deposited on the surface of the cross-linked gelatin sponge rather than uniformly distributed throughout the gelatin of the

subsequently foamed sponge. The structure results in the claimed decrease in hydration time relative to the untreated sponge.

As illustrated in the experimental section of the pending application and noted in the paper of August 3, 2010, the wetting agent Tween 60, specifically cited in the disclosure of Pawelchak, causes premature foam collapse (Table 5) when incorporated directly into the foaming composition, as disclosed by Pawelchak, under conditions taught by the pending application; however when coated onto the surface of a preformed sponge as taught by the pending application and claims, deposition from a non-aqueous solvent does not significantly collapse a preformed and cross-linked foam and provides the benefit of reducing hydration time from 6 minutes to 24-35 seconds (Table 2) - a hydration time reduction of 90-93% with a wetting agent which was not otherwise usable in the sponge producing process taught by Correll.

At no time does Pawelchak teach the use of a non-aqueous solvent and thus the sponge of Pawelchak, with or without a dispersed surface tension modifier therein, does not disclose a sponge having a coating deposited on the surface of a sponge from a non-aqueous solvent. Pawelchak does not disclose that a surface tension modifier, added "to stabilize the gas suspension and enhance the quality of the foam", has an effect on the hydration time of a sponge when incorporated uniformly throughout the sponge as opposed to being present as a surface coating. Pawelchak fails to describe each and every element as set forth in the claim and the invention is not shown in as complete detail as is contained in the claim. Appellant respectfully requests that the rejection of claim 22 be overruled.

2. Conclusion.

Claims 23-25, 27-30, 32, 33, and 42, which depend from claim 22 and add significant limitations thereto, are believed to be not anticipated by Pawelchak. Appellant respectfully requests that the rejections be overruled.

C. CLAIM 26 IS PATENTABLE OVER PAWELCHAK ET AL., U.S. PATENT NO. 4,292,972, IN VIEW OF YASUSHI ET AL., JP 02-182259, UNDER 35 U.S.C. § 103(a).

1. *All words in a claim must be considered in judging the patentability of that claim against the prior art.*

With regard to the rejections of claim 26 over Pawelchak in view of Yasushi et al. (JP 02-182259), the Advisory Action notes that “Yasushi is relied upon for the solely [sic] teaching of specific wetting agents as claimed by claim 26 and Song is relied upon for the solely [sic] teaching of inclusion of growth factor in wound dressing as claimed by claim 31”. Accordingly, Yasushi does not overcome the deficiencies of Pawelchak as applied to independent claim 22 which does not include that limitation.

2. *If an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious.*

Claim 26, which depends from nonobvious independent claim 22, also is believed to be nonobvious and Appellant respectfully requests that the rejection be overruled.

D. CLAIM 31 IS PATENTABLE OVER PAWELCHAK ET AL., U.S. PATENT NO. 4,292,972, IN VIEW OF SONG ET AL., EP 0 568 334, UNDER 35 U.S.C. § 103(a).

With regard to the rejection of claim 31 over Pawelchak in view of Song et al. (identified as EP 5568 334 (‘334), but believed to be EP 0 568 334), the Advisory Action notes that “Yasushi is relied upon for the solely [sic] teaching of specific wetting agents as claimed by claim 26 and Song is relied upon for the solely [sic] teaching of inclusion of growth factor in wound dressing as claimed by claim 31”. Accordingly, Song does not overcome the deficiencies of Pawelchak as applied to independent claim 22 which does not include that limitation. Claim 31, which depends from nonobvious independent claim 22, also is believed to be nonobvious and Appellant respectfully requests that the rejection be overruled.

E. CONCLUSION.

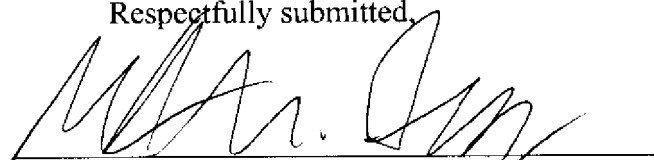
For the reasons stated above, claims 22-33 and 42 are properly supported under 35 U.S.C. § 112, first paragraph; claims 23, 27-30, 32, 33, and 42 are not anticipated by Pawelchak et al.; claim 26 is nonobvious over Pawelchak et al. in view of Yasushi et al.;

claim 31 is nonobvious over Pawelchak et al. in view of Song et al.; and the Examiner's rejections of claims 22-33 and 42 under 35 U.S.C § 112, § 102, and § 103 should be overruled.

Respectfully submitted,

Date:

Dec. 7, 2010

A handwritten signature in black ink, appearing to read "Glenn M. Seager", written over a horizontal line.

Glenn M. Seager, Reg. No. 36,926
SEAGER, TUFTE & WICKHEM, LLC
1221 Nicollet Avenue, Suite 800
Minneapolis, Minnesota 55403-2420
Glenn.Seager@stwiplaw.com
Tel: (612) 677-9050
Fax: (612)359-9349

VIII. CLAIMS APPENDIX

1-21. (Canceled)

22. A biocompatible, hemostatic, cross-linked gelatin composition comprising:

a preformed cross-linked gelatin sponge; and
a wetting agent;

wherein the wetting agent decreases hydration time of the gelatin sponge and the wetting agent is soluble in a non-aqueous solvent;

wherein the wetting agent is coated on at least a substantial portion of the surface of the preformed gelatin sponge by soaking the preformed gelatin sponge in a coating solution including the wetting agent and the non-aqueous solvent.

23. The biocompatible, hemostatic, cross-linked gelatin composition of Claim 22, wherein the gelatin composition is bioabsorbable.

24. The biocompatible, hemostatic, cross-linked gelatin composition of Claim 22, wherein the wetting agent is an anionic wetting agent.

25. The biocompatible, hemostatic, cross-linked gelatin composition of Claim 22, wherein the wetting agent is selected from the group consisting of ether capped polyoxyalkylenes, ester capped polyoxyalkylenes, polyethylene oxides, carboxymethyl cellulose, polyvinyl alcohol, polyvinyl pyrrolidone, sorbitan esters, phosphatides, alkyl amines, and glycerin.

26. The biocompatible, hemostatic, cross-linked gelatin composition of Claim 22, wherein the wetting agent is selected from the group consisting of alkyl (C₆-C₂₀) sulfate salts, aryl (C₆-C₁₀) sulfate salts, and alkaryl (C₇C₂₄) sulfate salts.

27. The biocompatible, hemostatic, cross-linked gelatin composition of Claim 22, wherein the gelatin composition comprises from about 0.01 to about 5 weight percent of the wetting agent.

28. The biocompatible, hemostatic, cross-linked gelatin composition of Claim 22, wherein the solvent from the coating solution is thereafter evaporated.

29. The biocompatible, hemostatic, cross-linked gelatin composition of Claim 22, wherein the coating solution comprises from about 0.01 to about 20 weight percent of the wetting agent.

30. The biocompatible, hemostatic, cross-linked gelatin composition of Claim 22, wherein the gelatin composition is sterilized and packaged for use in surgical procedures.

31. The biocompatible, hemostatic, cross-linked gelatin of Claim 22, wherein the gelatin composition further comprises a growth factor.

32. The biocompatible, hemostatic, cross-linked gelatin of Claim 22, wherein the gelatin composition further comprises a thrombus enhancing agent.

33. The biocompatible, hemostatic, cross-linked gelatin of Claim 22, wherein the gelatin composition further comprises an antimicrobial agent.

34. A method for hydrating a biocompatible, hemostatic, cross-linked gelatin composition, comprising the steps of:

providing an aqueous solution;

providing a cross-linked gelatin composition including a cross-linked gelatin sponge and a wetting agent, wherein the wetting agent is coated on at least a substantial portion of the surface of the gelatin sponge and decreases hydration time of the gelatin sponge; and

contacting the gelatin composition with the aqueous solution.

35. The method of Claim 34, wherein the wetting agent is coated on at least a substantial portion of the surface of the gelatin sponge by soaking the gelatin sponge in a coating solution including the wetting agent and a solvent, and evaporation of the solvent from the coating solution.

36. The method of Claim 35, wherein the coating solution comprises from about 0.01 to about 20 weight percent of the wetting agent.

37. The method of Claim 34, wherein the gelatin composition comprises from about 0.01 to about 5 weight percent of the wetting agent.

38. The method of Claim 34, wherein the gelatin composition is bioabsorbable.

39-41. (Canceled)

42. The biocompatible, hemostatic, cross-linked gelatin composition of Claim 22, wherein the wetting agent is selected from a group consisting of polyoxyalkylenes.

43. A hemostatic compound delivery system, comprising:
a cross-linked gelatin sponge comprising a wetting agent;
wherein the wetting agent decreases hydration time of the gelatin sponge and the wetting agent is soluble in a non-aqueous solvent;
a saline solution; and
a syringe assembly.

44. (Canceled)

45. The system of claim 43, wherein the syringe assembly comprises a holding chamber, an injection port, an ejection port, and a cannula.

46. The system of claim 45, wherein the injection port is a luer hub.

47. The system of claim 43, wherein the system is adapted to combine the saline solution and the gelatin sponge in the holding chamber and subsequently eject the sponge.

IX. EVIDENCE APPENDIX

No additional evidence has been presented.

X. RELATED PROCEEDINGS APPENDIX

None.